UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,113	01/09/2002	Ronald L. Ream	112703-201	9176

29156 7590 06/15/2004

BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135

EXAMINER	
HOWARD, SHARON LEE	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,113	REAM ET AL.	
	Examiner	Art Unit	
	Sharon L. Howard	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's arguments filed on 2/20/2004 have been considered but are moot in view of the new grounds of rejection.

Applicant argues that the Cherukuri ('838) reference lacks any disclosure or suggestion to motivate one of ordinary skill in the art to provide a product containing a coating which includes a medicament, and there is no disclosure or suggestion in Cherukuri that the coating comprises at least 50% by weight of the product.

Claims 8 and 16 are currentl amended.

Claims 8-20 are pending.

Claim Rejections - 35 USC § 112

Claims 8 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 8 and 16, it is suggested that applicant change the word "including" to "comprising".

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-11,14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Alkire et al. (U.S. Patent No. 5,607,697).

Alkire clearly anticipates applicant's claimed invention. The reference teaches taste masking microparticles for oral dosage forms or orally ingested solid dosage forms (see col.1, lines 6 and 7). Alkire discloses that each microparticle has a core which comprises a pharmaceutical agent and a taste-masking compound, including a binder and/or other excipient which may also be disposed within the core wherein the core is coated with a coating material such as ethylcellulose (see col.3, lines 11-13) which will retard dissolution of the pharmaceutical agent surrounding at least a portion of the core (see col.2, lines 57-67, bridging col.3, lines 1-5). Alkire teaches that the dosage form is completely disintegratable in the mouth so as to release the microparticles (col.3, lines 1-5). The dosage forms contemplated include microparticles having a core or center of pharmaceutical active agents such as drugs, vitamins, dietary supplements, granulated with, mixed with or adsorbed onto mannitol, using a suitable binder (see col.3, lines 6-16).

The reference teaches active agents such as antacids, dietary supplements, analgesics, anti-inflammatories, laxative, antibiotics, anorexics, decongestants and combinations thereof (see col.4, lines 57-67). The reference teaches the amount of the active agents can vary from a few milligrams to 2500 milligrams or more (col.5, lines 59-60). Alkire also teaches using taste masking agents and mannitol which defines the sugar alcohol (see col.5, lines 64-67). Alkire also discloses using sorbitol or xylitol and the like (see col.6, lines 12-16).

Alkire discloses artificial sweeteners such as aspartame and saccharin which may also be used in the composition, and that the amount of the sweetener used may depend on the size of the resulting microparticles, the size or volume of the resulting tablet or the amount of drug used, including other factors (see col.6, lines 24-41). The sweetener and active agent may be combined by the spray coating method and the sweetener may be used as an adsorbent for the active agent (see col.6, lines 45 and 46). The reference teaches protective coatings (see col.7, lines 5-43) and that the no more than about 50 percent of the weight of the microparticulate will be coating (see col.7, lines 40-43). The reference also teaches binders (see col.6, lines 47-50) or tablet binders which can be defined as an excipient, including up to about 20 weight percent of noneffervescent disintegrants such as sweeteners (see col.9, lines 1-6) which defines a taste-masking agent (see col.9, lines 55-67). Alkire discloses a pediatric cough/cold tablet formulation using active ingredients which have been microencapsulated with another encapsulated active (pseudoephedrine HCl) ingredient having no detectable drug aftertaste (See Example V, at col.14), comprising coated dextromethorphan HBr granulation, mannitol powder, aspartame and 8 mg/tab of prosweet powder.

The reference meets the claims of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to

> be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alkire ('697) in view of Kuhrts (U.S. Patent No. 5,096,714).

Alkire is discussed above.

Alkire does not teach that the tableted center includes dextrose.

However Kuhrts teaches sugars such as dextrose (col.9, line 66), and corn syrup solids, as well as sugar alcohols which include sorbitol, xylitol, mannitol, and the like which are known in the art for assisting disintegration of the tablet (col.9, lines 63-68, bridging col.10, lines 1 and 2). Kuhrts teaches a prolonged release drug tablet composition (see abstract) comprising a drug, vitamin, dietary food supplement, or other active therapeutic agent, which produces a unique, prolonged-action delivery system (col.8, lines 48-54). Kuhrts teaches sugars which are formulated into the composition to assist disintegration of the tablet. Kuhrts teaches drugs or therapeutic agents such as analgesics,

antihistamines, decongestants and caffeine which is a stimulant may be included in the composition (col.14, lines 31-53).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teaching of Alkire in the manner taught by Kuhrts. One having ordinary skill in the art would have been motivated to modify the composition of the Alkire reference to include dextrose, having the reasonable expectation of achieving a composition which is known in the art to be useful for the purpose of providing a microparticle having a core or center which is coated with a pharmaceutical agent, a sugar alcohol and dextrose.

Double Patenting

Claims 8-20 of this application conflict with claims 8-15,36-48 of Application No. 10/206,492. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 8-20 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 8-15,36-48 of copending Application No. 10/206,492 This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

No claims allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharon Howard
June 8, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600